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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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PATENT DEPARTMENT (51851)
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EXAMINER	
GISHNOCK, NIKOLAI A	

ART UNIT	PAPER NUMBER
3715	

MAIL DATE	DELIVERY MODE
11/24/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/657,144	ALEXANDER ET AL.	
	Examiner	Art Unit	
	NIKOLAI A. GISHNOCK	3715	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 October 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17,24,25,27,32,33,36 and 38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17,24,25,27,32,33,36 and 38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 September 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/8/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

In response to the Applicant's response of 10/8/2009, claims 1-16, 18-23, 26, 28-31, 34, 35, 37, 39, & 40 are cancelled. Claims 17, 24, 25, 27, 32, 33, 36, & 38 are pending.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 17, 24, 27, 32, & 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hon (US 4,907,973 A), hereinafter known as Hon, in view of Carlson et al. (US 5,820,600 A), hereinafter known as Carlson, and further in view of Garrison et al. (US 5,613,937 A), hereinafter known as Garrison.

4. Hon teaches an apparatus for simulation (an expert system simulator for modeling that is especially useful for training personnel in the medical and related arts, 1:7-9) comprising: a housing (internal arterial modeling device, 7:22-35; see Figure 9, Item 91); a mock anatomical site coupled to the housing having an orifice being configured to receive a peripheral device

(mock arterial paths having an inserted mock catheter, 7:50-60; see also Figure 9, Item 90 & Figure 10, Items 96, 96a, 96b, ... 96n & 97), the mock anatomical site being functionally coupled to a resilient hollow member or a pivotable torsion tube extending between the orifice and a sensing assembly, the hollow member being configured to guide the peripheral device between the orifice and the sensing assembly and disposed within a housing (representative internal model with mock arterial paths and mock catheter for realistic simulation of both the depth and feel of angioplasty. Sensors track the progress of the inserted catheter. Within or adjacent to the arterial pathway, magnetic ring sensors trace the direction and distance of catheter insertion; and a vessel constricting simulator is positioned in one or more desired locations along mock arterial path, 7:50-8:10) [Claims 17, 24, 32, 35, & 37].

5. What Hon fails to teach is a bracket positioned coupled to the mock anatomical site and the housing, having a first end coupled to a mock anatomical site and a second end coupled to a housing, configured to pivot at the second end to allow the mock anatomical site to be movable in a plurality of degrees of freedom with respect to the housing, to allow positioning adjustment of the mock anatomical site, and wherein at least a portion of the hollow member extends through a portion of the bracket [Claims 17, 24, & 32]. However, Garrison teaches a trocar for performing heart surgery (Figures 1-5), having a clamping device on the trocar sleeve to lock a retractor in position on a patient body and an adjustable collar for engaging the trocar sleeve to maintain retractor in position (all at 15:11-2). This clamp and collar assembly is understood to be an adjustable bracket. Garrison further teaches a shaft having proximal and distal ends, the shaft preferably a tube designed to fit within a hollow cannula's internal diameter to extend through the cannula, to reach a target site in a body cavity (15:25-40). A rod is extended axially through the shaft; the rod may further include axial lumens for fluid delivery (15:61-16:7). The bracket having a hollow shaft, or alternately, the rod incorporating a hollow

lumen, as taught by Garrison, would be used in the simulator of Hon for simulating real laparoscopic heart surgery procedures, such as fluid irrigation or removal. Therefore, it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have included the bracket of Garrison, having a hollow member extending through the bracket, in the surgical simulator of Hon, in order to more closely model a real surgical procedure including trocars, cannulae, and replicas of other devices used in real laproscopic surgery [Claims 17, 24, & 32].

6. What Hon further fails to teach is a first retainer coupled to a first end of the bracket proximal to a mock anatomical site; a first ring coupled to the mock anatomical site and the first retainer and configured to rotate about the first retainer; a first locking mechanism configured to prevent movement of the orifice when the locking mechanism is engaged in a locked position; a second retainer; a second ring coupled to the to the housing and the second retainer, the second ring being configured to rotate about the second retainer to allow the bracket to pivot with respect to the housing; and a hollow member extending through the resiliency-providing material and between the orifice and the housing and the sensing assembly, through the first retainer and first ring, the hollow member being configured to guide the peripheral device from the orifice to the housing and the sensing assembly [Claims 17, 24, 32, 35, & 37]. However, Carlson teaches an adjustable trocar valve (the valve is attached to the proximal end of a cannula shaft to form part of an introducer assembly, such as a trocar or a radially expandable introducer, for introducing instruments and viewing scopes through a percutaneous penetration into a patient's body, 4:15-19) having a first retainer (pivot tower, Figures 1 & 4, Item 40); a first ring disposed proximate to the orifice (dialator ring, Figures 1 & 4, Item 50), the first ring being configured to rotate about the first retainer (a second valve member or dialator ring is movably coupled around pivot tower, 7:34-49; also, 4:37-46); a first locking mechanism (holding

members, Figures 5A & 5B, Item 110) configured to prevent movement of the orifice when the locking mechanism is engaged in a locked position (the valve further includes means for securing a proximal portion of the instrument at or near the center of the membrane; the securing means comprises one or more holding members coupled to the first valve member for preventing transverse movement of the instrument relative to the membrane, while allowing axial movement, 4:47-55; thus preventing movement of the membrane, being part of the trocar and trocar stop assembly, e.g. the orifice, when secured, while the instrument is moved), and a bracket (introducer assembly including cannula shaft, Figure 1, Items 2 & 4) positioned between the mock anatomical site and the sensing assembly, through the first retainer and first ring, the hollow member being configured to guide the peripheral device from the orifice to the housing and the sensing assembly (introducer assembly generally includes an elongate shaft or cannula, a handle and a valve assembly; cannula has a proximal end, a distal end, and an axial lumen there between for receiving elongate objects, such as an endoscope and/or surgical instruments for performing a surgical procedure within the patient's body, 7:5-23), and allowing the mock anatomical site to pivot (4:27-55; to allow the mock anatomical site to pivot in a first direction with respect to the bracket, and in a second direction substantially orthogonal to the first direction are understood to be intended uses of the apparatus, and not given patentable weight); and wherein the locking mechanism uses at least one of a frictional force and a pressure force to prevent the movement of the orifice (Holding members are biased radially inward by a suitable biasing means, such as a spring, so that members secure the instrument at the center of membrane, 10:13-16; it is understood that the spring exerts a pressure force on the trocar and trocar stop, which is countered by friction from a normal force against the simulated instrument). The trocar and valve assembly of Carlson would be inserted into the mock arterial paths of Hon during a surgical simulation. The trocar assembly of Carlson would

be disposed as part of the assembly taught by Garrison to allow insertion of simulated instruments into a mock arterial site, such as a simulated artery. Therefore, it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have positioned the trocar as taught by Carlson, proximate to the bracket in the assembly taught by Garrison, in the apparatus for simulation of Hon, in order to increase the realism and accuracy of the training simulation [Claims 17, 24, 32, 35, & 37].

7. Claims 27 & 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hon, in view of Carlson and Garrison, and further in view of Lang et al. (US 5,480,307), hereinafter known as Lang.

8. Hon, Carlson, and Garrison teach all the features of claims 24 & 32, as demonstrated above. Hon teaches where in the housing is a mock torso (internal arterial modeling device, 7:22-35; see also Figure 9, Item 91). What Hon, Carlson, and Garrison fail to teach is wherein the mock anatomical site is a simulated patient head [Claim 27], or a mock face [Claim 36]. However, Lang teaches a training and practice apparatus for simulating and practicing clinical processes, having a model bust with a model head (Figure 1, Items 6 & 7), where the mock head has a face (Figure 2, Item 7), and is a mock anatomical site (FIG. 1 shows the model head in a supine disposition, viz. a working position in which clinical dental or orthodontic processes are carried out in the mouth area; this can take place by means of treatment instruments, which are individual treatment tools or treatment equipment connected to supply hoses, 5:8-30). The mock face of Lang would be mounted on the mock torso of Hon, as taught by Lang, to be used by inserting treatment instruments in the mock anatomical site. Therefore, it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have the mock anatomical site be a mock face, as taught by Lang, in the apparatus for simulation of Hon, as

taught by Carlson and Garrison, in order to increase the realism and accuracy of a simulation of facial surgery [Claims 27 & 36].

9. Claims 25 & 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hon, in view of Carlson and Garrison, as applied to claims 24 & 32 above, and further in view of Younker (US 5,951,301), hereinafter known as Younker.

10. Hon, Carlson, and Garrison teach all the features of claims 24 & 32, as demonstrated above. What Hon, Carlson, and Garrison fail to teach is where a block of resilient material is a block of foam [Claims 25 & 32]. However, Younker teaches a block of resilient material (synthetic torso, 4:20-34) that is a block of foam (a suitable elastomeric formula for making such a dry suture training procedure pack is a two part expandable urethane foam, 7:19-26). The modeling device of Hon would be formed of the resilient foam taught by Younker, for creating synthetic tissues that have a density, resiliency, and flexibility that approximates the corresponding mammalian tissue and reacts to mechanical forces in an equivalent fashion. Therefore, it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have used the block of resilient foam formed into a synthetic torso of Younker to form the internal arterial modeling device of Hon, in light of the teachings of Carlson and Garrison, in order to more precisely replicate the resiliency and reaction to mechanical forces encountered by a simulated endoscope [Claims 25 & 33].

11. Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hon, in view of Carlson and Garrison, as applied to claim 17 above, and further in view of Bailey (US 5,800,179), hereinafter known as Bailey.

12. Hon, Carlson, and Garrison teach all the features of claim 32, as demonstrated above. What Hon, Carlson, and Garrison fail to teach is wherein the peripheral device is a guidewire [Claim 38]. However, Bailey teaches a system for training persons to perform surgical procedures, having a mock surgical instrument (implement), coupled to a movement guide and sensor assembly, which contains a guide wire (the distal end of the implement within the housing is affixed to a movement guide and sensor assembly; collectively, the framed assembly with components described above, guide wire, and the guide rails form the movement guide and sensor assembly, 5:23-49). One of the endoscopic instruments simulated for insertion into the mock body of Hon would be an implement attached to a guide wire, as taught by Bailey. Therefore, it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have made the peripheral device of Hon a guide wire, as taught by Bailey, and further in light of the teachings of Carlson and Garrison, in order to restrict the motion of the implement within the housing and provide accurate sensing of the implement relative to that housing [Claim 38].

Response to Arguments

13. Applicant's arguments with respect to claims 17, 24, & 32 have been considered but are found unpersuasive. Regarding applicant’s argument that Hon, Carlson, and Garrison fail to teach a bracket that allows a mock anatomical site to be moveable with respect to the housing, Hon teaches a housing (internal arterial modeling device, 7:22-35; see Figure 9, Item 91); and a mock anatomical site coupled to the housing having an orifice being configured to receive a peripheral device (mock arterial paths having an inserted mock catheter, 7:50-60; see also Figure 9, Item 90 & Figure 10, Items 96, 96a, 96b, ... 96n & 97). Hon fails to teach is a bracket coupled to the mock anatomical site and the housing, configured to pivot at the second end to

allow the mock anatomical site to be movable with respect to the housing, wherein at least a portion of the hollow member extends through a portion of the bracket. What Garrison teaches a trocar for performing heart surgery (Figures 1-5), having a clamping device on the trocar sleeve to lock a retractor in position on a patient body and an adjustable collar for engaging the trocar sleeve to maintain retractor in position (all at 15:11-2). This clamp and collar assembly is understood to be an adjustable bracket. Garrison further teaches a shaft having proximal and distal ends, the shaft preferably a tube designed to fit within a hollow cannula's internal diameter to extend through the cannula, to reach a target site in a body cavity (15:25-40; see also 19:1-19). A rod is extended axially through the shaft; the rod may further include axial lumens for fluid delivery (15:61-16:7). The bracket having a hollow shaft, or alternately, the rod incorporating a hollow lumen, as taught by Garrison, would be used in the simulator of Hon for simulating real laparoscopic heart surgery procedures, such as fluid irrigation or removal. Therefore, it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have included the bracket of Garrison, having a hollow member extending through the bracket, in the surgical simulator of Hon, in order to more closely model a real surgical procedure including trocars, cannulae, and replicas of other devices used in real laproscopic surgery. In Garrison, Figure 2, the trocar is used to move an anatomical site into position for inserting surgical instruments into a patient with respect to the position of his body. This process is described in Garrison at 10:36-52. The clamp and collar assembly of Garrison repositions the anatomical site with regard to the rest of the patient's body by opening the site wide enough to pass an instrument through to the interior of the body. This bracket would just be used to clamp open the mock anatomical site of Hon. For these reasons, Garrison does suggest a bracket that allows a mock anatomical site to be moveable with respect to the housing in a plurality of degrees of freedom. Lang teaches a mock human head with an open mouth; it is apparent that the mock

mouth would be clamped open in a dental or esophageal procedure. Younker teaches using a foam block for the mock tissue, which would be used to better replicate real skin. Bailey further teaches using a guide wire, which would be used as it is in ordinary surgery. Thus, applicant's arguments are not convincing.

Conclusion

14. This is an RCE of applicant's earlier Application. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NIKOLAI A. GISHNOCK whose telephone number is (571)272-1420. The examiner can normally be reached on M-F 11:00a-7:30p EST (8:00a-4:30p PST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Xuan M. Thai can be reached on 571-272-7147. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

11/19/2009
/N. A. G./
Examiner, Art Unit 3715

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